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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,267	01/08/2004	Nancy E. Stagliano	MPI03-003P1RNOMNIM	6532

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BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,267	STAGLIANO ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 27, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicants' election of Invention I, claims 1-11, in the reply filed on November 27, 2006. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election is treated as an election without traverse (MPEP § 818.03(a)).

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected Inventions, there being no allowable generic or linking claim.

Currently, claims 1-11 are under examination.

Claim Rejections - 35 USC § 101

Section 101 of 35 U.S.C. reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claim 1 is directed to a method of detecting binding between a "compound" and a polypeptide corresponding to SEQ ID NO:20. According to Applicants' disclosure, such a "compound" is potentially specifically useful for treating disease.

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Applicants' asserted utility is based on observations concerning a *nucleic acid* corresponding to SEQ ID NO:19. Applicants detected¹ nucleic acid corresponding to SEQ ID NO:19 in various animal cells, and observed that the detected amounts of nucleic acid corresponding to SEQ ID NO:19 fluctuated in response to added chemicals, including cholesterol, fatty acid, Mevastatin, or Cerivastatin.

Applicants assert:

1. a nucleic acid corresponding to SEQ ID NO:19 "plays a role" in lipid metabolism.
2. a *polypeptide* corresponding to SEQ ID NO:20 "potentially plays a direct role" in cholesterol metabolism and/or lipid metabolism.
3. a compound that binds to a *polypeptide* corresponding to SEQ ID NO:20 is useful for treating disease.

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicants' asserted utility is not credible because Applicants' specification fails to disclose any data in support of assertion 2), *supra*.² That is, Applicants' specification does not disclose any evidence³ of any polypeptide, much less a polypeptide corresponding to SEQ ID NO:20, potentially "playing" any "role" in any metabolic system.

¹ Applicants detected nucleic acid corresponding to SEQ ID NO:19 using standard nucleic acid amplification techniques (*i.e.*, TaqMan™ RT-PCR).

² Please note, Examiner does not contest the notion that persons skilled in the art routinely practice the methods generally described in Applicants' specification for screening compounds. However, for the reasons set forth herein, Examiner does contest the quality and/or quantity of data regarding the specific application of those routinely practiced methods used to derive Applicants' claimed invention. Examiner posits that, based on the quantity of data (none) found in Applicants' disclosure, persons skilled in the art could not reasonably conclude that a polypeptide corresponding to SEQ ID NO:20 has utility for anything other than future characterization and validation studies. These further studies, however, are part of the act of invention and until performed, Applicants' claimed invention is incomplete.

³ According to Veenstra, 3 DRUG DISCOVERY TODAY 433 (2006), a determination of whether a polypeptide is a "deranged protein" that "plays a role" in a disease requires, *inter alia*, performing: (1) correlating RNA abundance versus protein abundance; (2) selecting suitable protein-containing samples; (3) optimizing fractionation protocols; (4) optimizing protein assays; (5) purifying pure protein; (6) performing preliminary binding assay; and (7) identifying structurally modifiable binding determinants (if any).

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A claimed invention must be useful in currently available form, which precludes any further experimentation to establish the utility of the claimed invention.⁴ A patent is not a hunting license.⁵

⁴ See MPEP 2107.01. A product invention lacks substantial utility if further research is necessary to study the properties of the product, so that a "real world" use may be identified or confirmed.

⁵ See *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689, 696 (US SupCt 1966).

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 7:

In step (b), the type mismatch "detecting binding[...] thereby identifying a compound" (paraphrasing mine) is indefinite. Whether the object(s) and/or steps required for performing "detecting" are coextensive with the object(s) and/or steps required for performing "identifying" is not clear. The identity of object(s) and/or step(s), if any, required for distinguishing "detecting" versus "identifying" is not clear.

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The claim preambles do not correspond to the method outcomes. Specifically, whether/how merely "detecting binding" amounts to a method of "identifying a compound capable of treating a cardiovascular disorder or a thrombotic disorder" is not clear.

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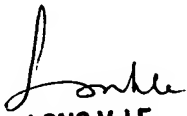
Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE 2/16/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600